

## REMARKS

All outstanding requirements will now be addressed in the order they appear in the Office Action mailed July 27, 2009.

### *Claim Rejections under 35 USC § 112*

Claims 11, 26, and 30 stand rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner alleges as follows: “The claims contain subject matter that the specification does not describe as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, possessed the claimed invention. This is a new matter rejection. Applicants point to no support in the specification as filed for the broadened definition of ‘free of the  $\beta$ -crystal form;’ the examiner finds none. The basis on which the purity is based or determined is undefined.”

In addition, claims 33-36 stand rejected under 35 USC 112, first paragraph, as allegedly not enabling, because they omit matter which the specification describes as essential to the invention as disclosed. These claims depend ultimately from canceled claims and have not been further treated on their merits.

Applicants respectfully disagree and submit that the subject matter of claims 11, 26, and 30 is well described in the specification as filed. Specifically, the specification does describe that the X-ray powder diffraction and IR spectra of the  $\alpha$ -crystal form of the methanesulfonic acid addition salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl]benzamide are different from those of the  $\beta$ -crystal form. See, e.g., [0021], [0054]-[0058], [0061]-[0065], and Figs. 1, 3, and 4.

In addition, claims 33-36 neither omit matter which the specification describes as essential to the invention as disclosed, nor they depend on canceled claims. Claims 33-36 depend on claim 1, which the Examiner considers allowable.

Claims 11, 26, and 30 stand rejected under 35 U.S.C. 112, second paragraph, as being allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Examiner alleges that “[i]t is not understood what is intended by the phrase ‘free of the  $\beta$ -crystal form.’ The basis on which the essential purity is based is not defined. It is also not understood how the purity is to be determined. If the reaction mixture is free of the  $\beta$ -crystal form as determined by X-ray powder diffraction, but not as determined by IR or DSC, or some other variation of these determinations, must the other forms of determination be also carried out?”

It appears that the Examiner did not consider Applicants’ amendments submitted on April 8, 2009. Specifically, the Examiner’s rejection is taken verbatim from the Office action of January 27, 2009, and includes reference to claim limitations that have been deleted from the claims (e.g., “DCS”). Applicants’ respectfully submit that Applicants’ amendment made on April 8, 2009 overcome the Examiner’s rejection under 35 U.S.C. 112, second paragraph.

Nevertheless, Applicants are cancelling claims 11, 26, 30, and 33-36 without prejudice to expedite the prosecution of the remaining claims, which the Examiner considers allowable. Applicants are not abandoning any rights to the subject matter of the canceled claims. Applicants reserve the right to prosecute the subject matter of the canceled claims in continuing applications.

In light of the present amendments, all rejections made in the Office actions of July 27, 2009 are now moot.

***CONCLUSION***

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 503182**.

Customer Number: **33,794**

Respectfully Submitted,

/Matthias Scholl/

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